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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,441	07/29/2003	Alastair Hodges	LFSCAN.079C1C1	8256
45416	7590	04/17/2006	EXAMINER	
LIFESCAN/NUTTER MCCLENNEN & FISH LLP 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 04/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,441

Applicant(s)

HODGES ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by French et al (Langmuir, 3-19-1998, 14, 2129-2133). French is being cited and relied on for the first time with this office action.
3. French discloses a metal electrode coated with a sulfur containing moiety (n-alkane thiols) that improves the temporal stability of the electrode (see the “Introduction”). French further teaches the presence of an overcoating of a surfactant (octanol) on the thiol layer. See the abstract and the last four lines of the Introduction.
4. With respect to the method of making the electrode, French first coats the electrode with the sulfur containing species and follows that with an overcoating of the surfactant. See “Monolayer Preparation” and “Electrochemical Experiments” on p. 2130.
5. With respect to the method of using the electrode (those limitations not covered above), French is monitoring the response of ferricyanide, which reads on the broadly defined obtaining a measurement indicative of an analyte.
6. Claims 1, 2, 6, 7, 10, 11, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweiss et al (CAPLUS abstract for Material Science Forum (1998), pp. 287-

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288) with or without further evidence from either the instant invention or French. Schweiss is being cited for the first time with this office action.

7. Schweiss discloses an electrode coated with a sulfur containing thiol molecule and further teaches that this electrode is exposed to “[a]dsorption and desorption kinetics of different surfactants *onto/from the surface of gold electrodes covered by self-assembled monolayers*” (emphasis added). This indicates that Schweiss recognized that the surfactants were forming an overlayer on top of the monolayer (i.e. coating) of thiol. Alternatively, the instant invention evidences that a combination of thiol and surfactant inherently form the set forth coating and overcoating by nature of the preferential binding of sulfur species to the electrode surface leaving the surfactant to form an overcoat (see p. 4, ll. 7-14). Furthermore, French evidences that surfactants form an overcoating over a thiol layer as well (see rejection above). Hence, because Schweiss forms a monolayer of thiol and exposes that to a surfactant solution (like the instant invention and French), an overcoating of surfactant would inherently result.

8. With respect to a hydrophilic group, the thiols utilized by Schweiss (16-Mercaptohexadecanoic acid and 20-Mercaptoeicosane-1-thiol) are terminated with carboxyl and amine groups respectively with alkyl spacers. See the attached Registry report for these two molecules.

9. With to the method of making the electrodes (those limitations not covered above), Schweiss first applies the monolayer coating followed by the surfactant (see the abstract).

10. With respect to the broadly claimed method of using, Schweiss is utilizing the electrode for the monitoring of surfactant analytes.

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11. Claims 1, 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al (Bioelectrochemistry and Bioenergetics, 42 (1997), pp. 7-13). Dong is being cited and relied on for the first time with this office action.

12. Dong discloses an electrode comprising a coating of alkanethiol (i.e. a sulfur containing moiety) with an overcoating of a lipid molecule. See fig. 9 and the section 3.3. The examiner is of the opinion that a lipid molecule would read on surfactant because it would reduce the surface tension between the hydrophobic monolayer and the water solution by virtue of its hydrophobic tail and hydrophilic head. The examiner notes that surfactants, including applicant's own Triton-X, typically consist of hydrophilic heads with hydrophobic tails.

13. With respect to claim 18 (those limitations not covered above), Dong teaches painting the lipids onto the monolayer containing electrode to result in the overlayer. See section 3.3.

14. With respect to claim 19 (those limitations not covered above), Dong teaches measuring the presence of sodium, potassium and lithium ions.

#### ***Claim Rejections - 35 USC § 103***

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claims 1-7, 10-13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of French.

17. With respect to claim 1, Allen discloses a coated metal electrode comprising numerous different sulfur-containing moieties for said coating. See p. 72 for a discussion of the metal electrode and table 1 for a listing of the moieties being relied on. Allen does not explicitly

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disclose overcoating this coating with a surfactant. French the desirability of adding a surfactant to the monolayer so as to improve the barrier properties of the monolayer itself. to prevent species from leaking through defects in the monolayer thereby forcing the electrochemistry to proceed through the sulfur-containing moiety (i.e. direct electron transfer). See the Introduction of French. It is noted that Allen is utilizing the sulfur-containing moiety as a direct electron transfer means (see the Introduction) and would benefit from the removal of defect related electron transfer. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of French for the electrode of Allen so as to prevent defect related electron transfer.

18. With respect to claims 2-4, see structures 2, 19 and 46 from fig. 3.
19. With respect to claim 5, see elements 28-30 of Table 1.
20. With respect to claims 6 and 7, see structures 4, 10a, 14a-16a from fig. 3.
21. With respect to claims 10 and 11, see structure 4 from fig. 3.
22. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Allen teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.
23. With respect to claim 13, see elements 7 and 28 from table 1.
24. With respect to claim 18 (those limitations not covered above), French teaches exposing the electrode to the surfactant after the application of the monolayer of thiol (see 102 rejection with French above).
25. With respect to claim 19 (those limitations not covered above), Allen utilizes the electrode as a measurement means for determining the presence of cytochrome c in the solution

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(see abstract, pp. 72-75 and fig. 1). This would read on the claimed “obtain a measurement indicative of a presence of an analyte in the sample”.

26. Claims 1, 2 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlereth et al (Electroanalysis 1995, 7 (1), pp. 46-54) in view of French.

27. With respect to claim 1, Schlerich discloses a coated metal electrode where the metal electrode comprising a coating of a sulfur containing moiety comprising cysteine. See Abstract and Scheme 1. Schlerich does not explicitly disclose the use of an overcoating of surfactant. French teaches the addition of a surfactant to a monolayer coated surface so as to form a overcoating that seals in the defects of the monolayer thereby preventing the contact with interfering electroactive species. See rejection above and note that Schlerich repeatedly teaches that monolayer surface coverage was low (i.e. high concentration of defects) (see section 3.1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of French for the electrode of Schlerich so as to prevent the interference from other electroactive species.

28. With respect to claim 2, see scheme 1 of Schlereth.

29. With respect to claims 6-9 and 13, see the cysteine of scheme 1.

30. With respect to claims 10 and 11, scheme 1 also shows examples of alkyl and aromatic spacers.

31. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Schlereth teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

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32. With respect to claims 14-17, cysteine is inherently a stereospecific molecule. Although Schlereth does not specify which form of cysteine is present, Schlereth discusses no criticality as to the choice of isomer is present and one possessing ordinary skill in the art would have been motivated to utilize either the D or L isomer (or both) because they would all provide the desired monolayer for the electrode.

33. With respect to claim 18 (those limitations not covered above), French teaches exposing the electrode to surfactant after the application of the monolayer of thiol (see 102 rejection with French above).

34. With respect to claim 19 (those limitations not covered above), Schlereth utilizes the electrode to obtain a measurement of phenothiazine or NADH. See section 1 or 3.1. This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

### ***Response to Arguments***

35. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753  
April 13, 2006



**KAJ K. OLSEN**  
**PRIMARY EXAMINER**